1644

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1644

In re Patent Application of

Richard B. Mazess, et al.

Serial No. 09/402,636

Filed: April 26, 2000

Examiner: Phillip Gambel, Ph.D.

I, Diane J. Frauchiger, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the date of my signature.

Diane J. Frauchiger
Signature

February 13 2001
Date of Signature

"TARGETED THERAPEUTIC DELIVERY OF VITAMIN D COMPOUNDS"

Sir:

Transmitted herewith is a Response to Restriction Requirement in the above-identified application.

Applicant claims small entity status

The fee has been calculated as shown below.

CLAIMS AS AMENDED							
	(1)	(2) CLAIMS REMAINING AFTER AMENDMENT	(3)	(4) HIGHEST NO. PREVIOUSLY PAID FOR	(5) PRESENT EXTRA	(6) RATE	(7) ADDITIONAL FEE
	TOTAL CLAIMS	40	MINUS	40	0	X $9	0.00
	INDEP. CLAIMS	6	MINUS	6	0	X $40	0.00
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT ----▸			0.00

* If the entry in Column 2 is less than the entry in Column 4, write "0" in Column 5.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

No additional fee is required.
Charge or credit Deposit Account No. 50-0842 with any shortage or overpayment of the above fee. A duplicate copy of this sheet is enclosed. IN NO EVENT CAN THE ISSUE FEE BE CHARGED TO THE DEPOSIT ACCOUNT.

Respectfully submitted,

Teresa J. Welch
Reg. No. 33,049

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Michael Best & Friedrich LLP
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Group Art Unit 1644

In re

Patent Application of

Richard B. Mazess, et. al.

Serial No. 09/402,636

Filed: April 26, 2000

Examiner: Phuong N. Huynh, Ph.D.

"TARGETED THERAPEUTIC DELIVERY OF VITAMIN D COMPOUNDS"

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February 13 2001
Date of Signature

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to an Office Action, mailed December 13, 2000, Applicants respectfully request reconsideration of a restriction requirement and of statements comparing the claimed invention to two prior art references, in view of the following remarks. Transmitted herewith is a fee and a petition for a one month extension of time, extending the shortened statutory time for response to the Office Action from January 13, 2001 to February 13, 2001.

I. RESPONSE TO RESTRICTION REQUIREMENT

The Office Action begins by stating that:

> Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372: This application contains the following invention or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. (Office Action, p. 2, paragraph 2).

The Office Action goes on to divide the forty claims of the application into five groups of claims.

A. Standard of Review for Restriction of U.S. National Phase Applications

PCT Rule 13.1, cited above, defines the Unity of Invention requirement applied by the International Searching Authority prior to preparation of an International Search Report. Applicants respectfully submit that the Unity of Invention standard is not the proper standard under which U.S. patent applications are examined, including patent applications (such as the present one) which entered the U.S. through the PCT, under 35 U.S.C. §371. Nonetheless, Applicants submit that even though PCT Rule 13.1 does not apply to the examination of an international application once it enters National Phase in the U.S., all the claims of the present application are sufficiently linked to "form a single general inventive concept", for reasons set forth below. Furthermore, Applicants respectfully submit that restriction under 35 U.S.C. §121 is not justified, because the claims of the present application are not directed to two or more independent and distinct inventions. Restriction is also unwarranted in the present case because all the claims are directed to or include an element of a conjugate of vitamin D in U.S. class/subclass 552/653. Subject matter falling within a single subclass can be examined by a single examiner.

B. Restriction and Election

In the Office Action, the Examiner divided the forty claims of the application into five groups of claims, and restricted the Applicants to prosecution of one of the five groups of claims. (Office Action, p. 2). The Examiner also required election of a specific target molecule moiety from a list of such moieties on page 3 of the Office Action (citing list of target moieties disclosed on p. 9 of the Specification). Election of a specific bone-seeking agent was required, where appropriate (e.g. when claim 31, which recites such an agent, is one of the claims elected). (Office Action, p. 3). Finally, election of a specific

therapeutic/cytotoxic agent was required, where appropriate (e.g. when claims 17, 18, or 34 are among the claims elected).

Applicants hereby provisionally elect with traverse the claims of Group I (claims 1-22), all of which are drawn to a "conjugate comprising at least one vitamin D moiety associated with a target molecule moiety having an affinity for a tissue of interest" (language of claim 1). Applicants also provisionally elect to prosecute claims directed to the vitamin D conjugates of the present invention, wherein the target molecule is a bisphosphonate moiety for bone. In the event that claim 31 of Group III is prosecuted herein, Applicants provisionally elect the bone-seeking agent, bisphosphonate. When the conjugate further comprises a therapeutic agent other than a vitamin D moiety, Applicants provisionally elect "a bone-therapeutic agent" which consists of "conjugated estrogens or their equivalents" (language of claim 18). Applicants make all of these elections with traverse, for the following reasons.

C. Reasons Why Restriction is Improper In This Case

At the outset, Applicants would respectfully point out that although the Examiner has asserted that the present application is directed to five independent and distinct inventions, the Examiner has not provided a single class or subclass in which the alleged separate inventions fall. Without such guidance from the Examiner, Applicants can only assume that inventions do not fall in separate classifications, do not have a recognized separate status in the art and do not require different fields of search.

All the claims of the present application are either directed to or include an element of a "conjugate comprising at least one vitamin D moiety associated with a target molecule moiety having an affinity for a tissue of interest." (See language of independent claims 1, 20, 23, and symbolic representation of such a conjugate in claims 28, 32, and 34). That element

is a "single general inventive concept", under PCT Rule 13.1. It is also the inventive concept which unifies all the embodiments of the invention expressed in each of the independent claims of the application, such that the independent claims and the claims which depend therefrom are not directed to "independent and distinct inventions".

Applicants also submit that it would not place an undue burden on the U.S. Patent and Trademark Office to examine all the claims in the same application, given the common structural features of the vitamin D conjugate element of each claim, cited above. As noted above, conjugates of vitamin D all fall into U.S. class/subclass 552/653. Applicants also submit that each of the species in the genus of target molecule moieties, therapeutic/cytotoxic agents, and bone-seeking agents cited in each of the respective claims serve the same function as other species in the same genus. Thus, despite structural differences between members of the same genus, Applicants respectfully submit that it would not place an undue burden on the PTO to examine each claim as a whole, including all the species of target molecule moieties, therapeutic/cytotoxic agents, and bone-seeking agents cited in certain claims of the application.

III. REMARKS ABOUT PRIOR ART REFERENCES CITED

The Office Action also included comments about Peterson *et al.* (U.S. Pat. No. 5,691,328) and Bouillon *et al.* (U.S. Pat. No. 5,232,838), two references cited in the International Search Report. The two references were cited as demonstrating that "the invention of Group I has been previously described." (Office Action, p. 3).

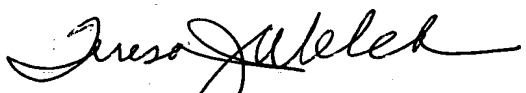
Applicants respectfully submit that neither reference, whether viewed separately or together, teaches or suggests the vitamin D conjugate of claim 1 and of all the other claims in Group I. Specifically, both references fail to teach or suggest the target molecule moiety element of the vitamin D conjugate of claim 1.

Applicants note that no statutory basis for rejection of any of the claims of the present invention, under U.S. law was provided. Absent any such rejection, Applicants respectfully defer a detailed discussion of the patentability of any of the present claims in view of Peterson *et al.* and/or Bouillon *et al.* until at least some of the claims have been rejected.

IV. SUMMARY

For reasons set forth above, Applicants respectfully provisionally elect, with traverse, the claims of Group I (claims 1-22), target molecule moieties which are a bisphosphonate moieties, and bone-therapeutic agents which consist of conjugated estrogens or their equivalents. Applicants respectfully submit that all the claims of the present application (i.e., claims 1-40) are in a condition for allowance. Should the Examiner have any questions about the application, or suggestions as to ways in which the language of the claims could be improved upon, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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Docket No.: 17620-9277

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